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Application No.	990107
Date of Filing	15 February, 1999
Applicant	ATROPOS LIMITED, an Irish company of 1 Earlsfort Centre, Hatch Street, Dublin 2, Ireland.

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

Dated this 9 day of December 1999.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

FORM NO. 1

950107

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

__X__ the grant of a patent under Part II of the Act

_____ the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. Applicant(s)

Name ATROPOS LIMITED

Address 1 Earlsfort Centre
Hatch Street
Dublin 2
Ireland

Description/Nationality

An Irish company

2. Title of Invention

"A surgical device"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date	Country in or for which filed	Filing No.

4. Identification of Inventor(s)
Name(s) of person(s) believed
by Applicants(s) to be the inventor(s)

Name: Frank Bonadio, a citizen of the United States of America.
Address: 2 Martello Terrace, Bray, County Wicklow, Ireland.

Name: Derek William Young, an Irish citizen.
Address: 3 Cloister Way, Carysfort Avenue, Blackrock, County Dublin, Ireland.

990107

5. Statement of right to be granted a patent (Section 17(2) (b)

The Applicant derives the rights to the Invention by virtue of a Deed of Assignment dated February 12, 1999.

6. Items accompanying this Request – tick as appropriate

(i) __X__ prescribed filing fee (£100.00)

(ii) __X__ specification containing a description and claims

____ specification containing a description only

__X__ Drawings referred to in description or claims

(iii) ____ An abstract

(iv) ____ Copy of previous application (s) whose priority is claimed

(v) ____ Translation of previous application whose priority is claimed

(vi) __X__ Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant (s)

7. Divisional Application (s)

The following information is applicable to the present application which is made under Section 24 –

Earlier Application No: .....

Filing Date: .....

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

Name	Address
John A. O'Brien & Associates	The address recorded for the time being in the Register of Patent Agents, and currently Third Floor, Duncairn House, 14 Carysfort Avenue, Blackrock, Co. Dublin, Ireland.

9. Address for Service (if different from that at 8)

As above

Signed _____ JOHN A. O'BRIEN & ASSOCIATES

Date February 15, 1999

"A Surgical Device"

Introduction

The invention relates to a sealing device having a lumen for an article and integral sealing means for sealingly engaging an article passing though the lumen. More particularly, but not exclusively the sealing device is a surgical device such as a forearm seal for use by a surgeon carrying out hand assisted laproscopic surgery.

Various sealing devices are known however some conventionally sealing devices are either of complex construction, are difficult to use and/or do not provide an efficient seal.

There is therefore a need for an improved sealing device.

Statements of Invention

According to the invention there is provided a sealing device comprising:

a substantially tubular sleeve of pliable material which is turned axially back on itself to define an outer sleeve section and an inner sleeve section;

the inner and outer sleeve sections defining therebetween a sealed distensible chamber;

the inner sleeve section defining a lumen; and

the inner sleeve section, on distension of the chamber, sealingly engaging an object extending through the lumen.

In a preferred embodiment of the invention the sleeve is twisted prior to forming the sealed chamber.

The chamber may be inflated by gas, such as air pressure. The chamber may also be distensible by a liquid or a flowable material generally.

In one embodiment of the invention the sealing device includes mounting means for the sleeve.

Preferably the mounting means comprises a first and second mounting means attached at different locations to the sleeve.

The first mounting means may be attached to one end of the sleeve and the second mounting means may be attached to the other end of the sleeve.

Preferably the mounting means are movable relative to one another for twisting the sleeve. Ideally, the mounting means are rotatable relative to each other for twisting the sleeve.

In a preferred embodiment of the invention each mounting means comprises a ring.

In one embodiment of the invention the sealing device includes locking means for locking the first mounting means relative to the second mounting means.

Ideally, in this case the sealing device includes a port for inflation of the chamber.

The sealing device is preferably for use in a surgical procedure. For example the sealing device may be a forearm seal for use in surgical procedures.

In a preferred arrangement the sealing device includes an attachment means for attaching the sealing device to another device. Alternatively the other device may be integral with the sealing device. The other device may be another surgical device such as a wound protector, a wound retractor, a wound protector retractor.

In a preferred embodiment of the invention the inner mounting means is of a resilient material.

Preferably the inner mounting means is an O-ring seal.

In a particularly preferred embodiment of the invention a wound engaging portion of the connecting means has a greater flexibility than that of a main body of the connecting means.

In one embodiment of the invention the inner mounting means has a diameter which is greater than a diameter of the outer mounting means.

Ideally the inner mounting means includes engagement means for engaging an inner wall of a patient at a wound opening.

Typically the engagement means comprises an engagement lip which extends radially outwardly and axially of the inner mounting means.

Most preferably the engagement means is of a resilient material.

The sealing device may be used for other medical/surgical uses. For example, it may be used as a roll up device for use in limb surgery in moving up the blood through the limb. The device could also be used as splint.

Brief Description of the Drawings

The invention will be more clearly understood from the following description thereof given by way of example only with reference to the accompanying drawings, in which:-

Fig. 1 is a perspective view of a sealing device according to the invention;

Fig. 2 is a cross sectional view of the device of Fig. 1;

Fig. 3 to 5 are perspective and side views illustrating one use of the sealing device of Figs 1 and 2 as a forearm seal;

Figs 6 to 8 are perspective and side views illustrating one use of the sealing device in association with another surgical device;

Figs 9 to 12 are perspective views illustrating one method for forming the device of Figs 1 and 2; and

Figs 13 to 17 are diagrammatic views used to explain the invention.

Fig. 18 is a side cross sectional view of another surgical device;

Fig. 19 and 20 are diagrammatic perspective views illustrating the insertion of the device of Fig. 18 through a wound opening;

Fig. 21 is a perspective view of the device of Fig. 18 in position in a wound opening;

Fig. 22 is a side, partially cross sectional view of the device of Fig. 18 in use;

Fig. 23 is a perspective view of the device of Fig. 21 showing the entry of a surgeons hand;

Fig. 24 is a side, partially cross sectional view of the device of Fig. 21 in a different position of use;

Fig. 25 is an end view of the device in the position of Fig 24;

Fig. 25 is a perspective view of the device in the position of Fig. 24;

Fig. 27 is a perspective view of another surgical device according to the invention ;

Fig. 28 is a side cross sectional view of the device of Fig. 27 in position; and

Fig. 29 is a cross sectional view on an enlarged scale of portion of the device of Fig. 28.

Detailed Description

Referring to the drawings there is illustrated a sealing device 1 according to the invention which in this case is configured for use as a surgical device. The device in this instance, is for use as a seal for sealing a surgeon's forearm 2 on entry through a wound opening 3, for example in the abdominal wall 4.

The sealing device 1 comprises a substantially tubular sleeve 10 of pliable gas tight material such as a suitable biocompatible plastics material. The sleeve 10, as illustrated particularly in Figs 9 to 12 is turned axially back on itself to define an

outer sleeve section 11 and an inner sleeve section 12. The inner and outer sleeve sections 11, 12 define therebetween a sealed inflatable chamber 13. The inner sleeve section 11 defines a lumen 14 and, on inflation of the chamber 13, the inner sleeve 11 sealingly engages an object extending or passing though the lumen 14.

In this case the sleeve 10 is twisted prior to forming the sealed inflatable chamber 13. The twisting, as illustrated in Figs 9 to 12 may be carried out before the turning of the sleeve 10 axially back on itself to form the inner and outer sleeve sections 11, 12. Alternatively the twist may be formed in use.

The sealing device includes mounting means for the sleeve. The mounting means is in this case provided by a first mounting ring 20 to which one end of the sleeve 10 is attached and a second mounting ring 21 to which the opposite end of the sleeve 10 is attached. The mounting rings 20, 21 are movable, in this case rotatable relative to one another for twisting the sleeve 10. For illustrative purposes axially extending indictor lines 30 are drawn on the sleeve 10 in its initial tubular configuration. As the sleeve 10 is twisted on relative rotation between the rings 20, 21 the indicator line 30^{I} is also twisted. On turning of the sleeve 10 axially back on itself as illustrated in Fig. 11 the indictor line 30^{II} follows a twist pattern. However, on inflation of the chamber 13 defined between the sleeve sections 11, 12 the outer section of the indictor line 30^{III} is straightened so that it takes up a position which is parallel to the longitudinal axis of the sleeve 10 and formed lumen 14. As the outer sleeve section 11 untwists on inflation it follows that the inner sleeve section 10 is twisted more in response. As the outer sleeve section 11 has effectively no twist all the twist has been transferred to the inner sleeve section 12.

The rings 20, 21 may be locked together using an suitable locking means which may be releasable. The sealing device also includes a port 35 for inflation of the chamber 13.

The sealing device 1 has several uses which will be described in more detail below. One particular embodiment of its use is shown in Figs 3 to 5. As a surgeon inserts his forearm 2 through the lumen of the device 1 the inner sleeve section 12 rolls along with the arm 2 which in turn draws part of the outer tube section 11 through. Thus, an effective seal is maintained around a surgeons arm 2 and the sealed integrity of the body cavity being operated on is maintained. To facilitate insertion lubrication may be used.

In one case the device may be pre-twisted and inflated prior to or during use. Alternatively the device may be twisted when located in position and then inflated to form a highly effective seal.

The sealing device 1 may be used in association with another device such as another surgical device. One possible arrangement is diagrammatically illustrated in Figs 6 to 8. In this case the other device is a wound protector retractor 50 having a lumen 51 through which a surgeon passes his hand for hand assisted laproscopic surgery. The particular wound protector retractor illustrated is described in detail in our corresponding application entitled "A surgical device" and filled concurrently with this application. The whole contents of that application are incorporated herein by reference.

The other device may be integral with the sealing device of the invention.

The following detailed explanation is given to assist in a clearer understanding of the invention. The invention is not limited to this explanation.

<u>The Twisted Tube</u>

Consider the hollow cylindrical tube shown in Fig. 13. The wall of the cylinder defines a lumen through its center. Consider a linear element A-B. if the upper edge of the tube is rotated through some angle point A will move to the position

shown in the middle sketch. The element A-B will still define a straight line. The tube will distort into a nominally hour glass shape with a reduced lumen at mid height. The diameter of the lumen at the neck of the tube is dependant on the angle of twist. When the upper edge is rotated through 180° the lumen will close down to zero diameter. At any horizontal plane through a twisted tube the material must be wrinkled and hence under compressive hoop stress.

Lumen Diameter vs. Angle of Twist

Fig. 14 a shows the lumen diameter (D2) as a proportion of the tube diameter (D1)for angels of twist (E) from 0 to 180 degrees. The lumen diameter is calculated as:

$$D2 = D1 \cos(E/2).$$

As can be seen the lumen diameter is independent of the tube length

Elongate object passed through twisted tube

As can be clearly seen from Figs 14a and 14b the angle of twist necessary to collapse the lumen of a tube to the diameter of an elongate object passed therethrough is dependant on the ratio of the tube diameter and the diameter of the elongate object. The angle of twist can be calculated from:

$$\text{Cos.}^{-1}(E/2) = D2/D1$$

Where E = angle of twist

D1 = tube diameter

D2 = diameter of elongate object

Although depicted as of circular profile, a tube of sufficiently compliant material will conform to many non recursive profiles. For such a profile D2 is taken as the smallest diameter which can be inscribed within the profile.

Twin walled pressure vessels under internal pressure

Consider a thin walled tube as shown in Fig. 15a. One end of the tube is folded back on itself as shown in Fig. 15b and the fee ends conjoined. What is defined is essentially a twin walled tube (or two coaxial tubes conjoined at their ends) with an enclosed volume between the two walls. The introduction of a pressurised fluid into the enclosed volume will cause the outer tube to behave like a pressurised aircraft fuselage, that is it will be subject to tensile axial and hoop stresses. The inner tube will be subject to tensile axial stress and compressive hoop stress. As a result the lumen will collapse in to a nominally buck bill configuration but constrained by the outer tube.

Greater control of the lumen can be obtained by the introduction of a twist into the tube. The tube shown in Fig. 16a is twisted as shown in Fig. 16b. One end of the tube is folded back on itself, as shown in Fig. 16c, and the free ends conjoined. As in the previous example this configuration defines two coaxial conical vessels conjoined at their bases and at the apex. However the common apex is not constrained to remain in this configuration. In reality in the inner and outer tubes are free to behave as individual tubes each with half of the original twist and as such the composite tube can better be defined as two coaxial hour glass tubes as shown in Fig. 16d, each containing half the original total twist. As both the inner and outer tubes are necked they each are subject to compressive hoop stresses. The introduction of a pressurised fluid into the enclosed volume produces what is believed to be a novel response.

Firstly, consider the outer tube. It is a necked hour glass tube with compressive hoop stresses. The introduction of the pressurised fluid induces tensile hoop

stresses, negating the compressive hoop stresses induced by the twist. Since, to remain in its twisted configuration, the tube must have compressive hoop stresses and since the pressurised fluid overcomes these compressive stresses the tube must untwist and take on a nominally cylindrical configuration, see Fig. 16e. Since the inner and outer tubes are conjoined, as the outer tube untwists the inner tube twists more in response. Since the outer tube has not twist the inner tube must have all the twist. If the original total twist were 180° then the lumen would close totally. Additionally, the material defining the inner tube will be central within the diameter of the outer tube. This configuration will for brevity be called a Cyclops.

Possible Uses for Cyclops

Translation of an elongate object through a Cyclops

Consider the arrangement depicted in Fig. 17a. A shaft is passed through a Cyclops with the lumen closed down by the pressure until it is in mutual contact with the shaft. The outside diameter of the Cyclops is resting in mutual contact with a fixed surface. Consider points of contact A, between the Cyclops and the fixed surface, and B, between the shaft and lumen of the Cyclops. As the shaft is translated, as shown in Fig. 17b. Point A remains fixed whilst the leading end of the lumen rolls out. Since the Cyclops does not change in overall length the trailing end of outside diameter rolls in as depicted. It will be apparent that the shaft translates to the right twice as far as the Cyclops. This of course is exactly the motion of a caterpillar tract. From this point of view a Cyclops could be considered as a three dimensional caterpillar tract. Since points A and B on the Cyclops do not move relative to their corresponding positions on the shaft and the fixed surface there is no frictional resistance to the translation of the shaft. In Fig. 17c, the Cyclops has translated to the right by approximately its own length. The material which had originally formed the inner tube has rolled out to become the outer tube and vice versa. In other words the Cyclops has turned inside out. Since the inner tube of the Cyclops is in a twisted configuration and since the

point B remains in contact with the same point on the shaft rotates about it's axis as depicted by arrow C (in this instance approx. 120°). In order to obtain this translation the resistance required to be overcome is that generated as the leading and trailing ends of the Cyclops deform as they roll out and roll in respectively.

Referring to Figs 18 to 26 there is illustrated another surgical device 100 which in this case provides a wound protector retractor. In this case inner and outer mounting means are provided by O-rings 101, 102 respectively. The inner mounting O-ring 101 is of a suitable resilient elastomeric material for bunching of the ring 101 to facilitate ease of insertion into a wound 103 as illustrated in Figs 19 and 20.

A wound protector section 105 of the flexible sleeve 11 in this case is of a plastics sheet material that has a greater flexibility than that of the main body of the sleeve 11. In this way, on inflation of the sleeve 11 in use the protector section 105 stretches to conform most closely to the irregular shape of the wound 103. In addition, the inner ring 101 is drawn against the inner wall surrounding the wound, on inflation of the sleeve as will be particularly apparent from Figs 22 and 24. The arrangement also facilitates lubricated rotation of the protector section 105 of the sleeve which facilitates insertion of a surgeons arm.

The inner ring 101 preferably has a larger diameter than that of the outer ring 102 to create a tapering effect. This arrangement promotes a pressure differential which assists insertion of a surgeons arm acting against the internal abdominal pressure.

Referring to Figs 27 to 29 there is illustrated another surgical device 120 according to the invention which is similar to the device of Figs 18 to 26 and like parts are assigned the same reference numerals. In this case the inner ring has engagement means in the form of a radially and axially extending lip seal 125 to engage an

inner wall of a patient at the wound opening 103. This facilitates positive location and engagements of the device 120, in use.

The invention is not limited to the embodiments hereinbefore described which may be varied in construction and detail.

Claims

1. A sealing device comprising:

a substantially tubular sleeve of pliable material which is turned axially back on itself to define an outer sleeve section and an inner sleeve section;

the inner and outer sleeve sections defining therebetween a sealed distensible chamber;

the inner sleeve section defining a lumen; and

the inner sleeve section, on distension of the chamber, sealingly engaging an object extending through the lumen.

2. A sealing device as claimed in claim 1 wherein the sleeve is twisted prior to forming the sealed chamber.

3. A sealing device as claimed in claim 1 or 2 wherein the chamber is inflatable.

4. A sealing device as claimed in any preceding claim including mounting means for the sleeve.

5. A sealing device as claimed in claim 4 wherein the mounting means comprises a first and second mounting means attached at different locations to the sleeve.

6. A sealing device as claimed in claim 5 wherein the first mounting means is attached to one end of the sleeve and the second mounting means is attached to the other end of the sleeve.

7. A sealing device as claimed in claim 6 wherein the mounting means are movable relative to one another for twisting the sleeve.

8. A sealing device as claimed in claim 7 wherein the mounting means are rotatable relative to each other for twisting the sleeve.

9. A sealing device as claimed in any of claims 5 to 8 wherein each mounting means comprises a ring.

10. A sealing device as claimed in any of claims 5 to 9 including locking means for locking the first mounting means relative to the second mounting means.

11. A sealing device as claimed in any preceding claim including a port for inflation of the chamber.

12. A sealing device as claimed in any preceding claim for use in a surgical procedure.

13. A sealing device as claimed in any preceding claim which is a forearm and/or instrument seal for use in surgical procedures.

14. A device as claimed in any claims 5 to 13 wherein the inner mounting means is of a resilient material.

15. A device as claimed in claim 14 wherein the inner mounting means is an O-ring seal.

16. A device as claimed in any preceding claim wherein a wound engaging portion of the sleeve has a greater flexibility than that of a main body of the connecting means.

17. A device as claimed in any of claims 5 to 16 wherein the inner mounting means has a diameter which is greater than a diameter of the outer mounting means.

18. A device as claimed in any of claims 5 to 17 wherein the inner mounting means includes engagement means for engaging an inner wall of a patient at a wound opening.

19. A device as claimed in claim 18 wherein the engagement means comprises an engagement lip which extends radially outwardly and axially of the inner mounting means.

20. A device as claimed in claim 18 or 19 wherein the engagement means is of a resilient material.

21. A sealing device as claimed in any preceding claim including another device integral with the sealing device.

22. A sealing device as claimed in any preceding including an attachment means for attaching the sealing device to another device.

23. A sealing device as claimed in claim 21 or 22 wherein the other device is another surgical device.

24. A sealing device as claimed in any of claims 21 to 23 wherein the other device is a wound protector.

25. A sealing device as claimed in any of claims 21 to 23 wherein the other device is a wound retractor.

26. A sealing device as claimed in any of claims 21 to 23 wherein the other device is a wound protector retractor.

27. A sealing device substantially as hereinbefore described with reference to the accompanying drawings.

28. A surgical device substantially as hereinbefore described with reference to the accompanying drawings.

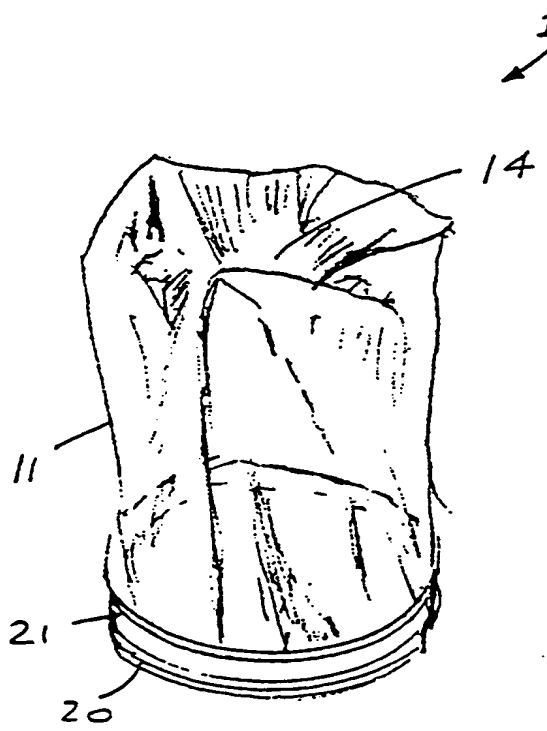

Fig. 1

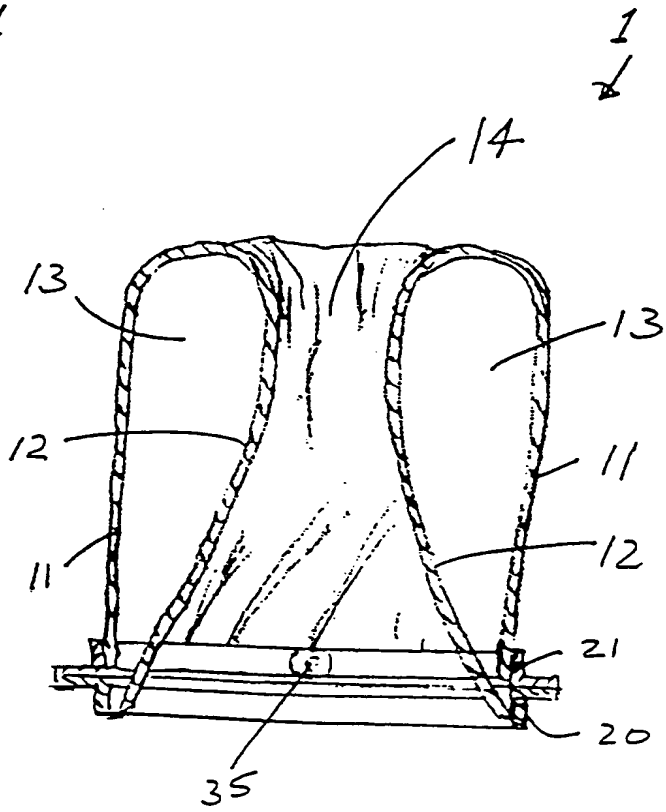

Fig. 2

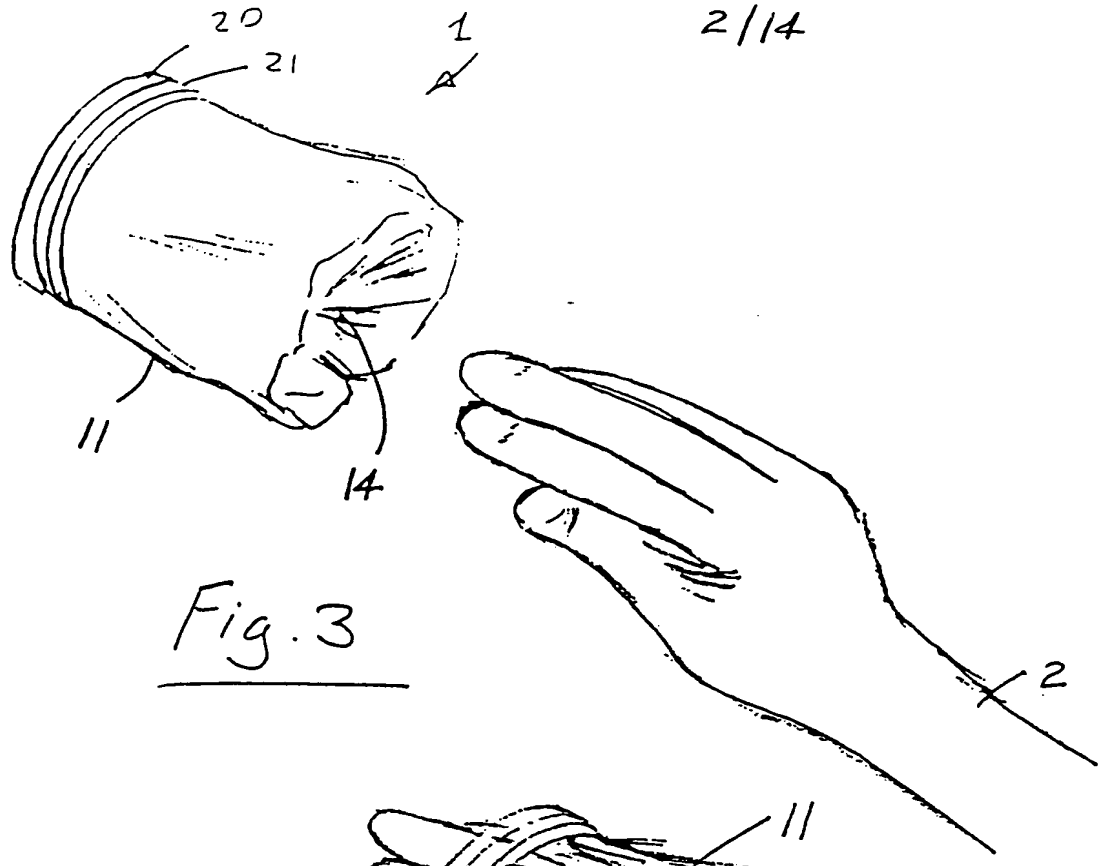

Fig. 3

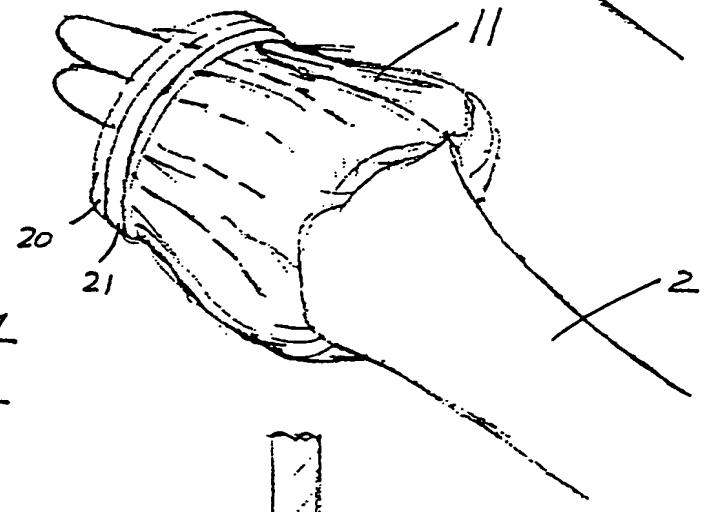

Fig. 4

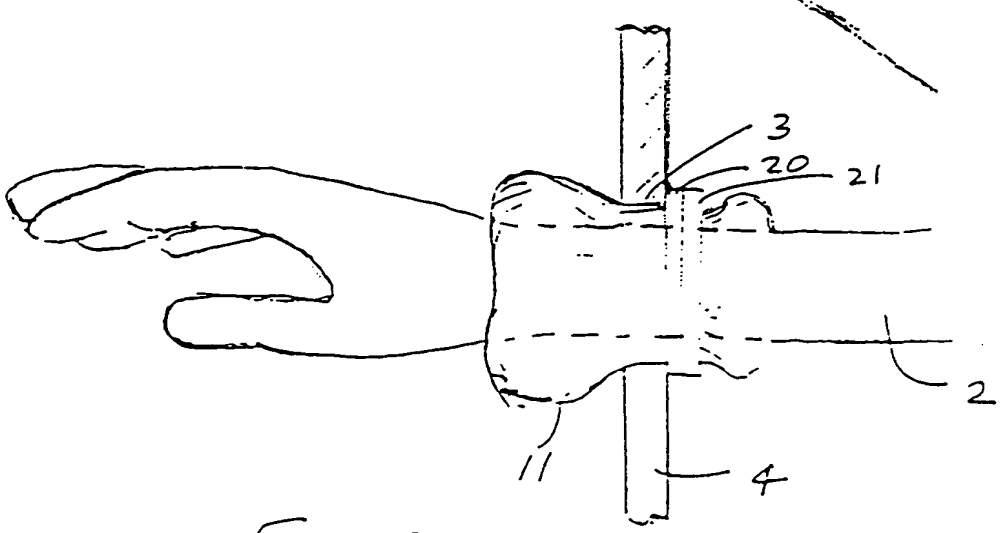

Fig. 5

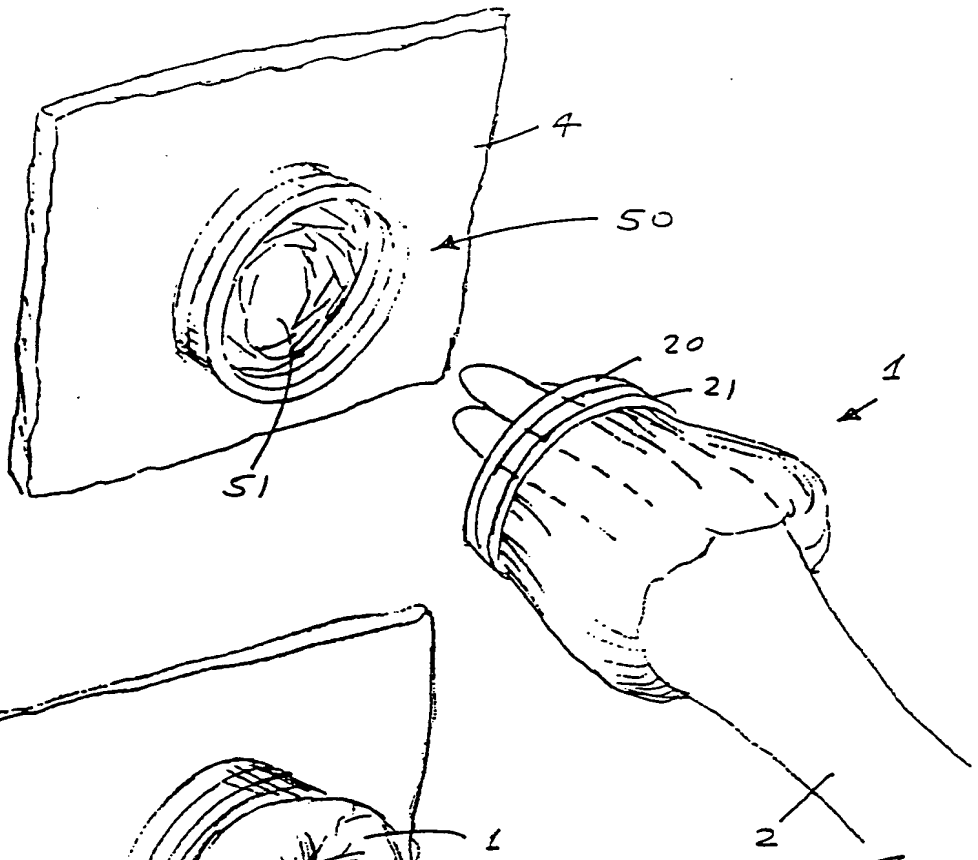

Fig. 6

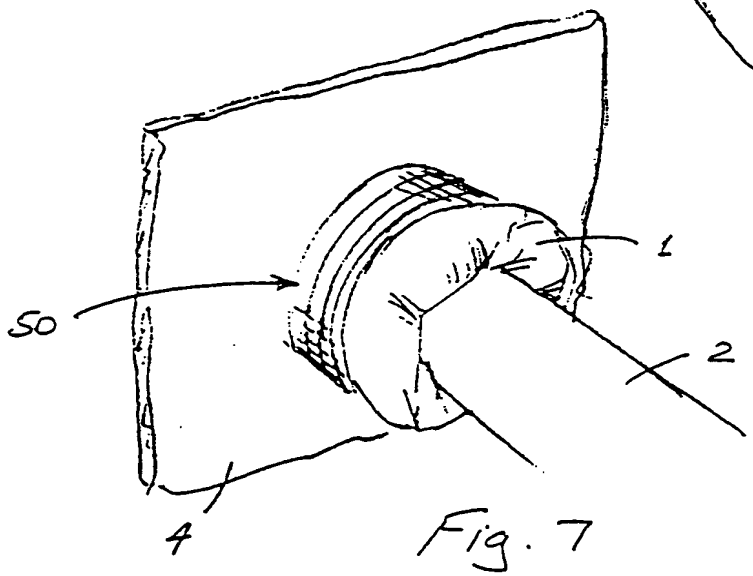

Fig. 7

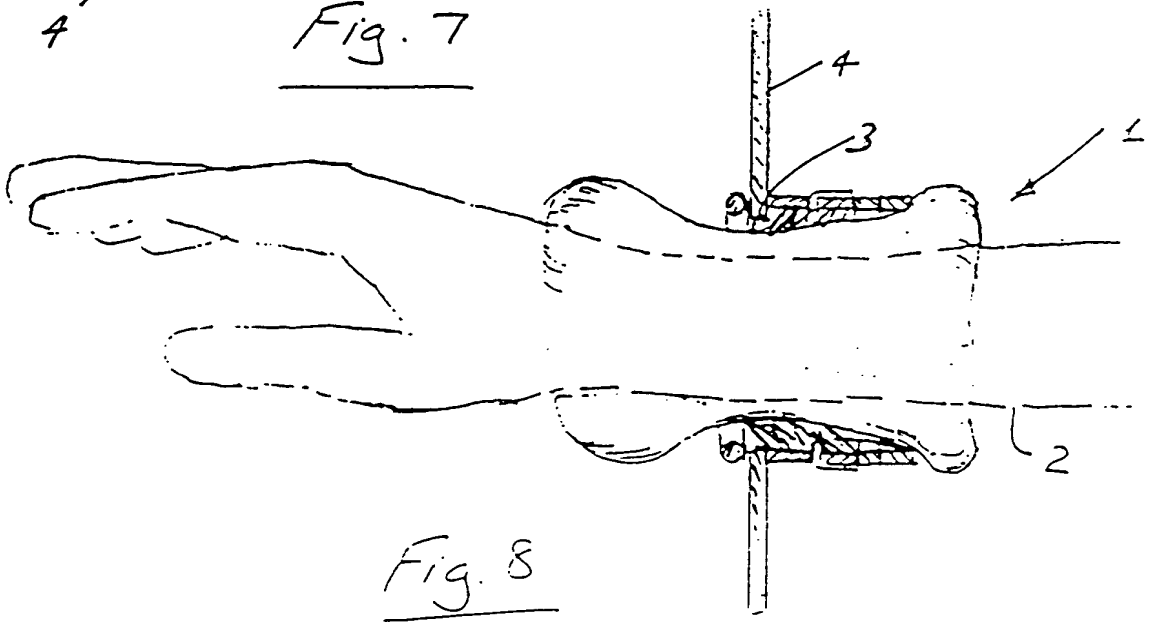

Fig. 8

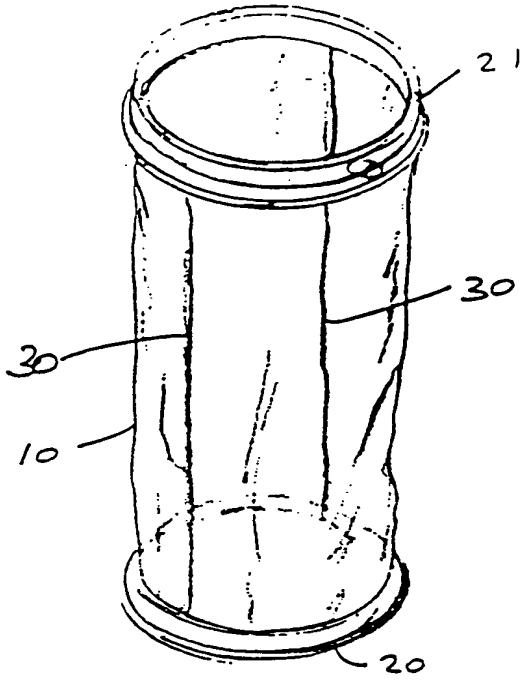

Fig. 9

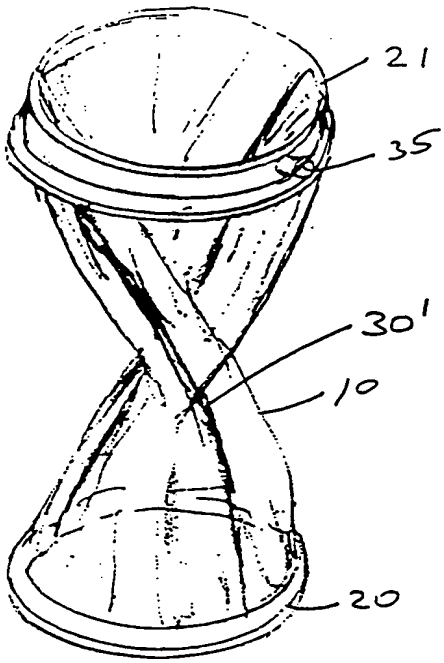

Fig. 10

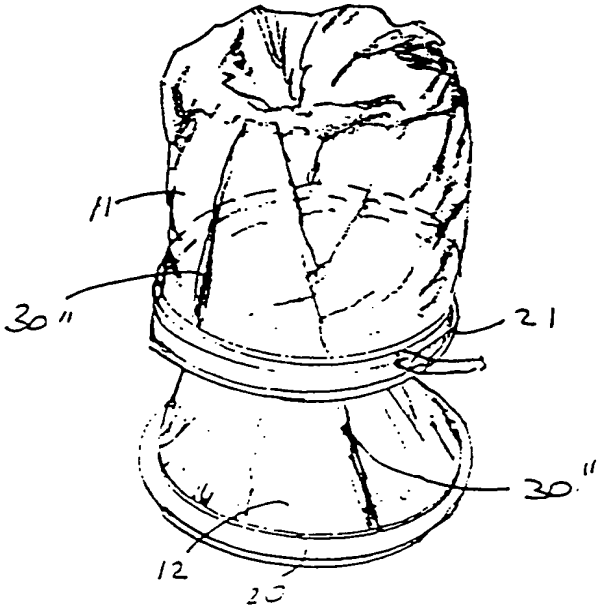

Fig. 11

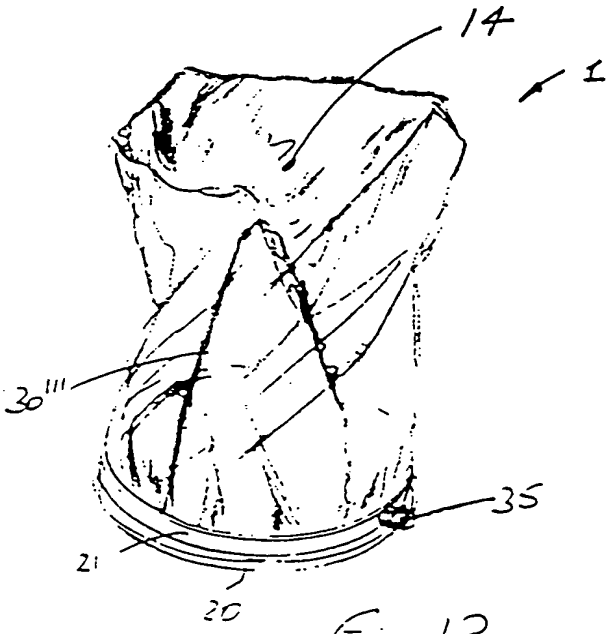

Fig. 12

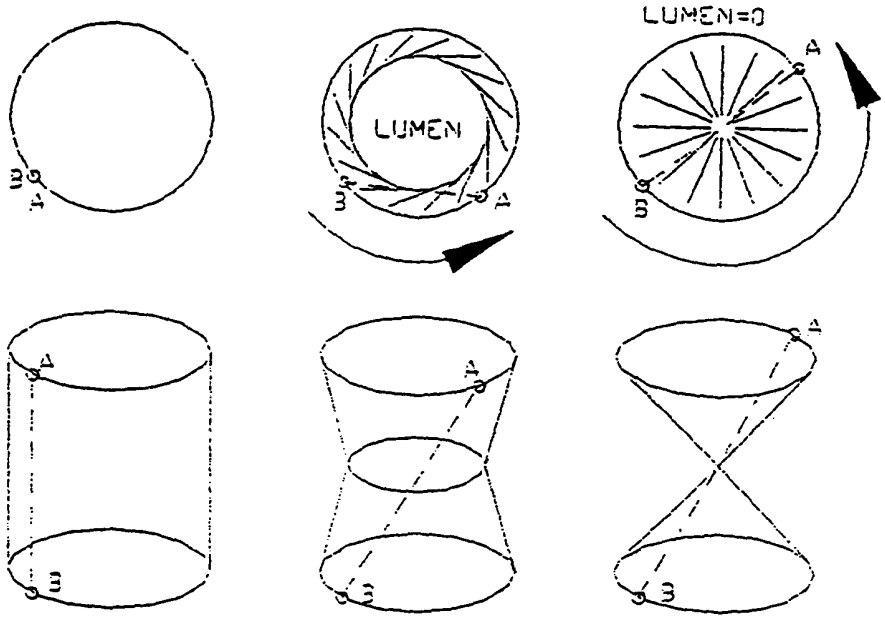

Fig.3 The Twisted Tube

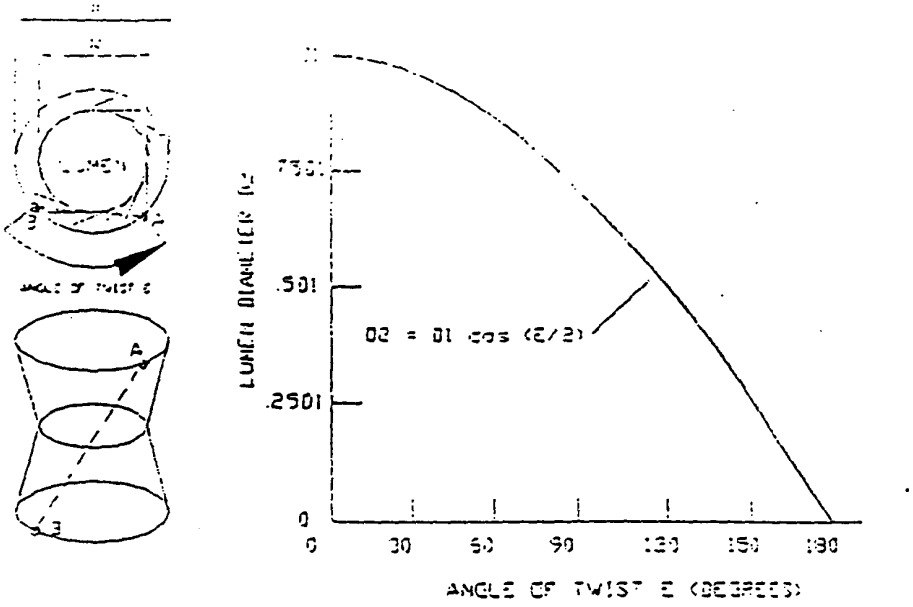

Fig. 4a. Angle of twist vs. lumen

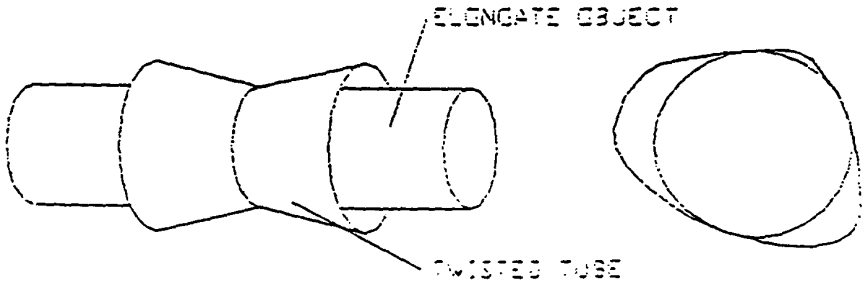

Fig. 4b Twisted tube with elongate object passing therethrough

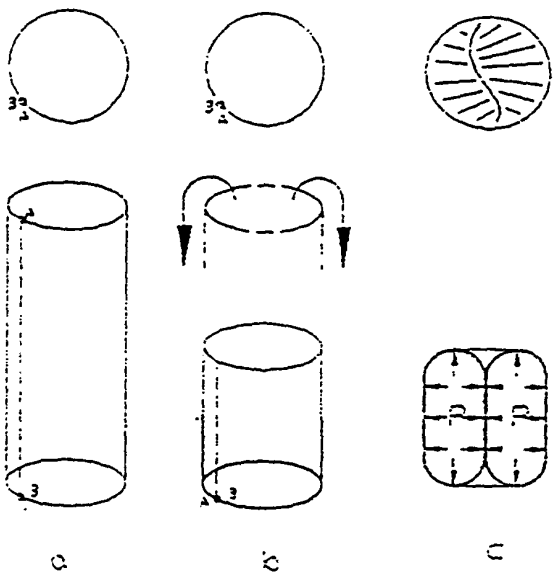

Fig.15 Twin walled vessel under internal pressure.

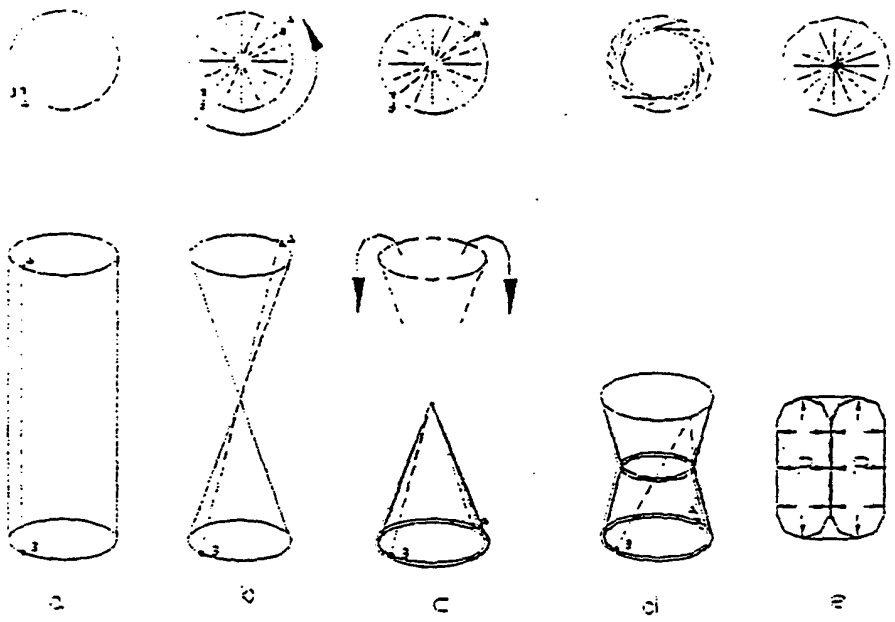

Fig.16 Twin walled tube with twist subject to internal pressure.

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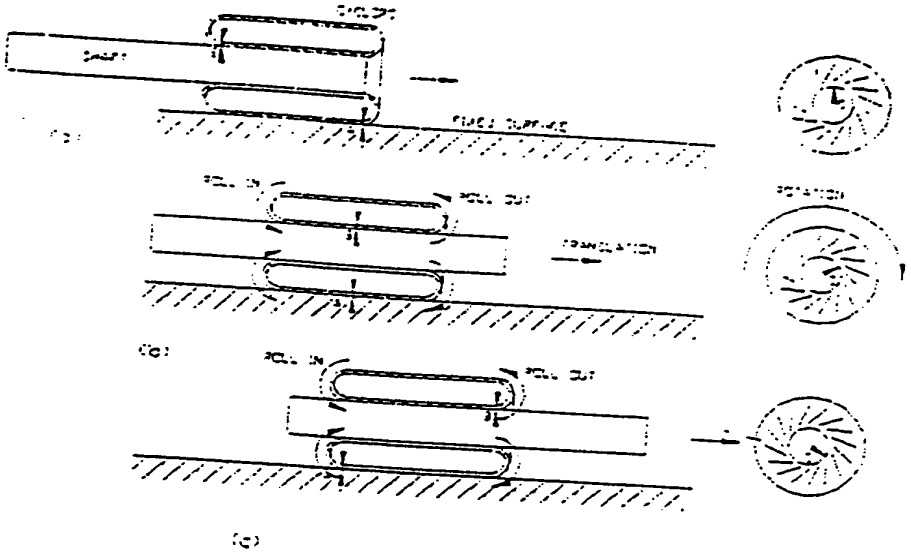


Fig17. Translation of a shaft within a Cyclops

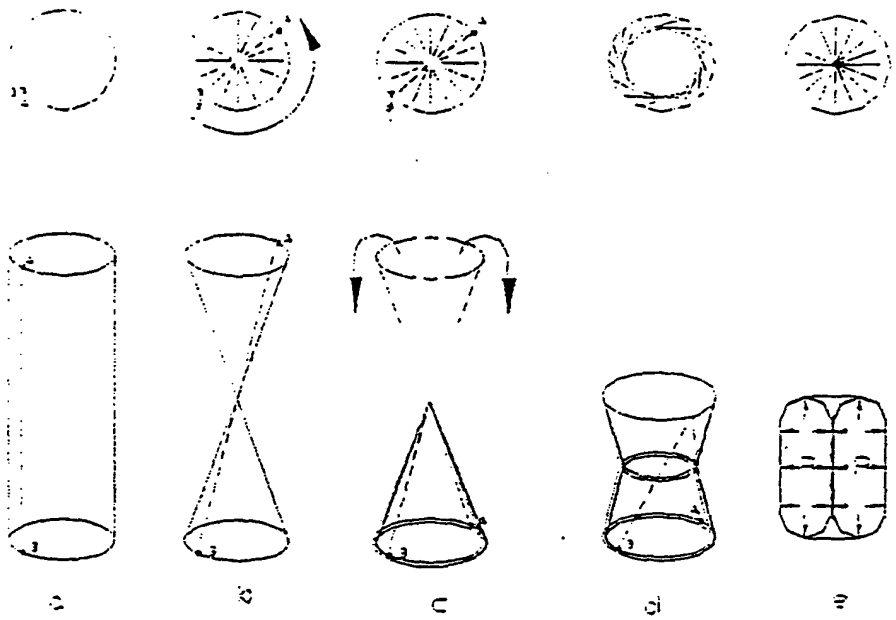


Fig.16 Twin walled tube with twist subject to internal pressure.

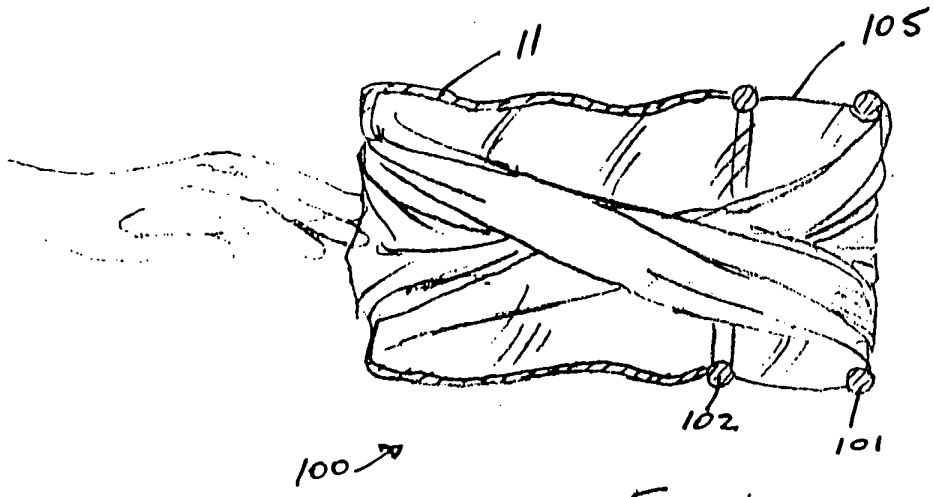


Fig. 18

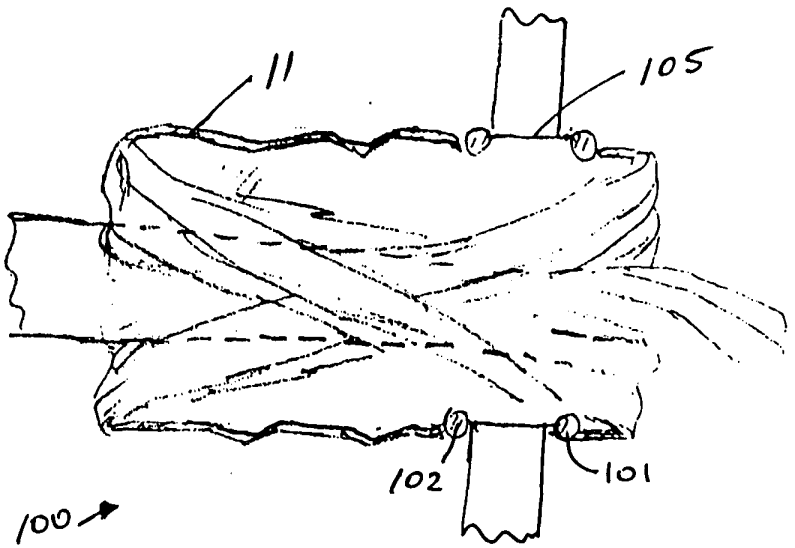


Fig. 22

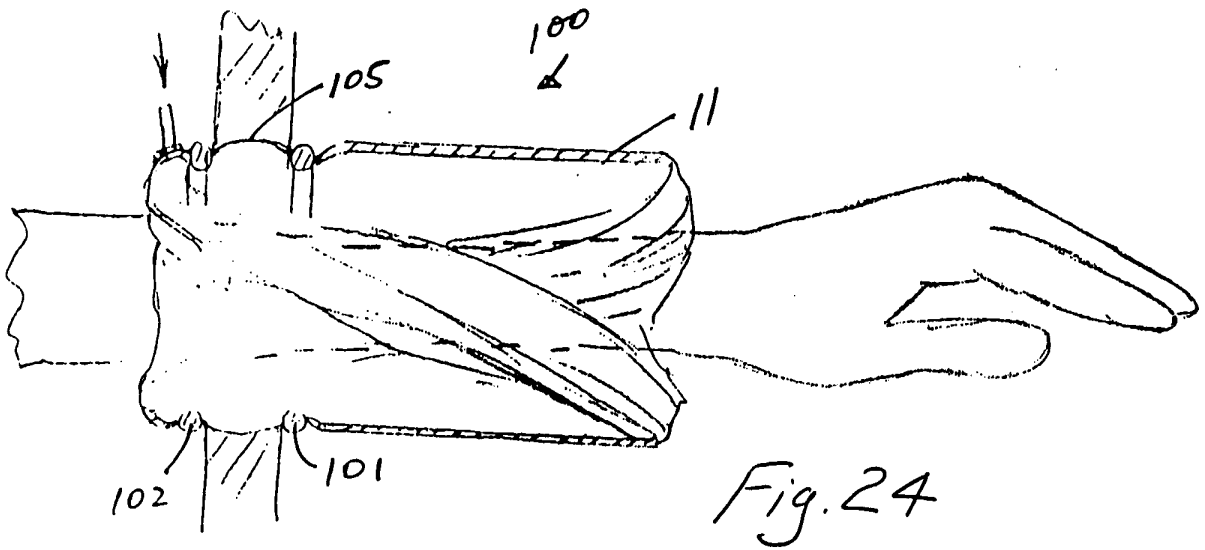


Fig. 24

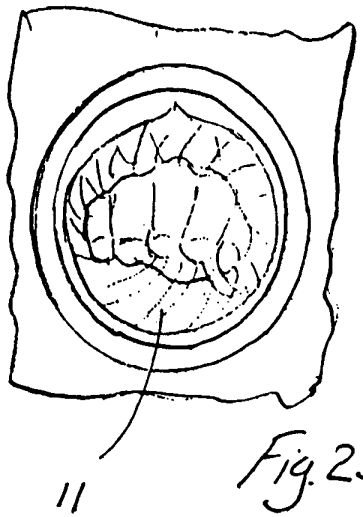


Fig. 25

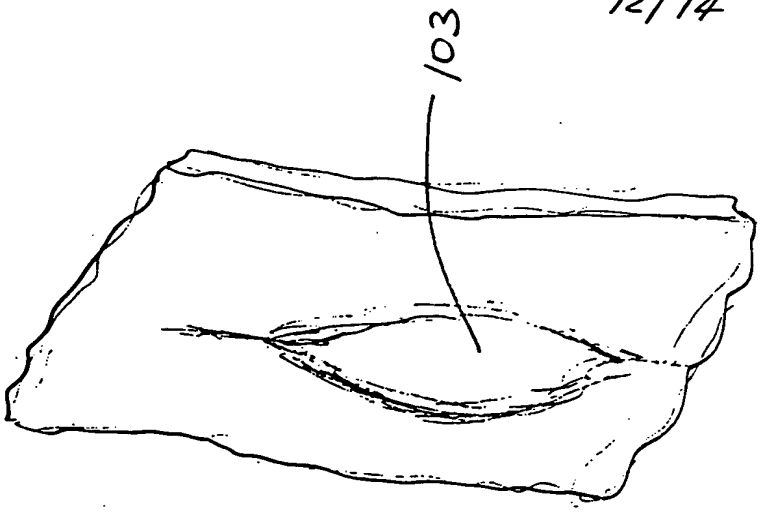


Fig. 19

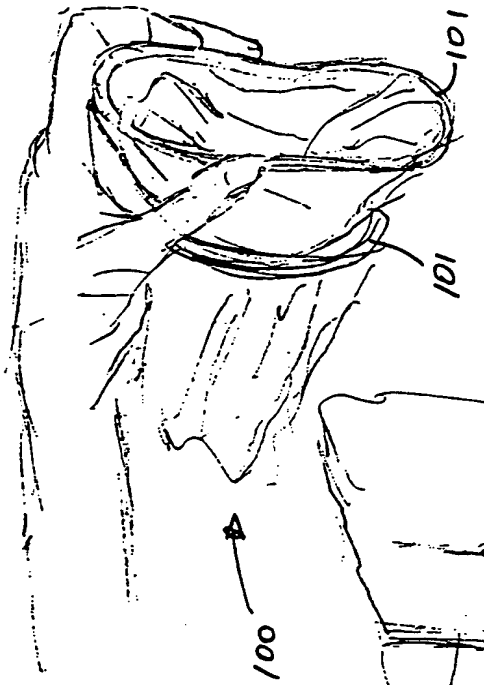
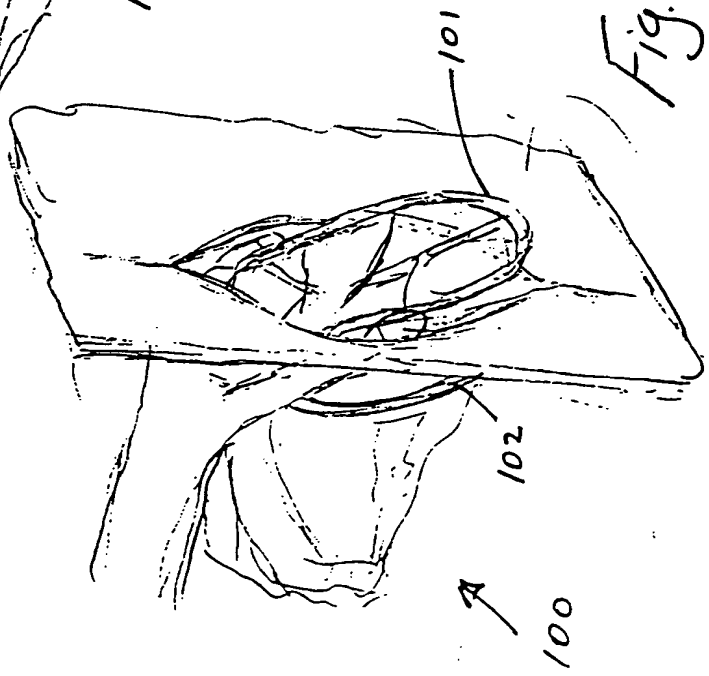


Fig. 20



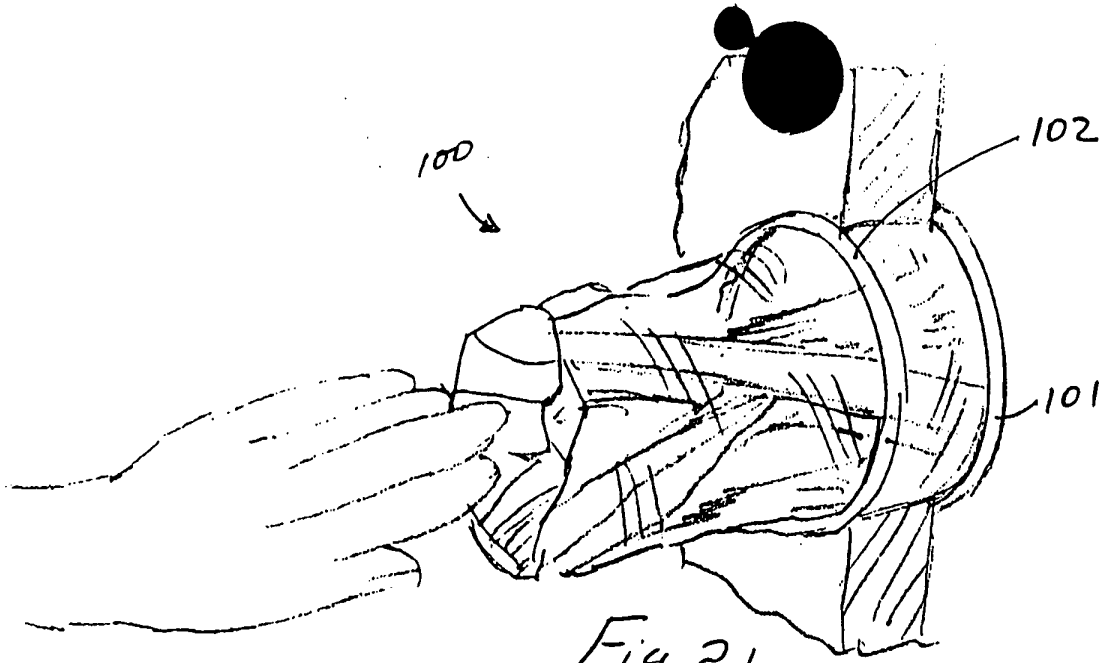


Fig. 21

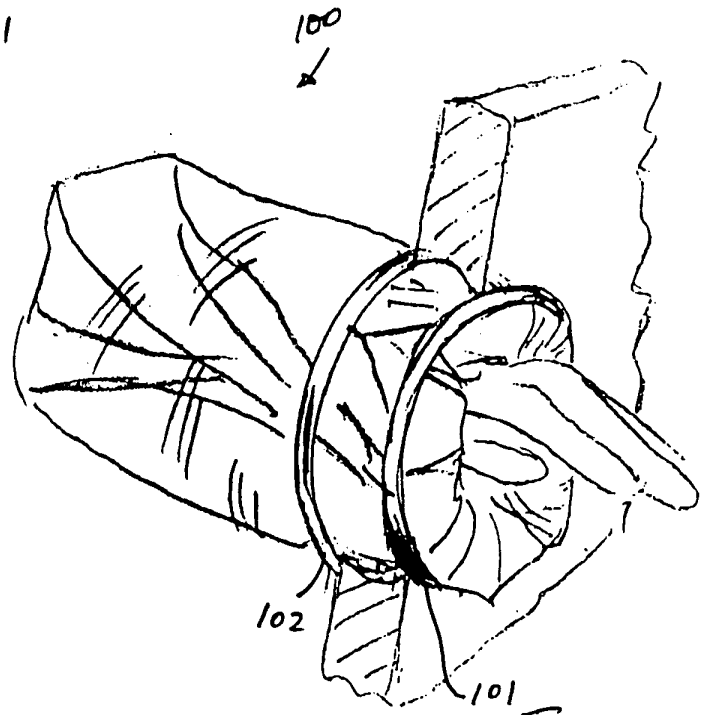


Fig. 23

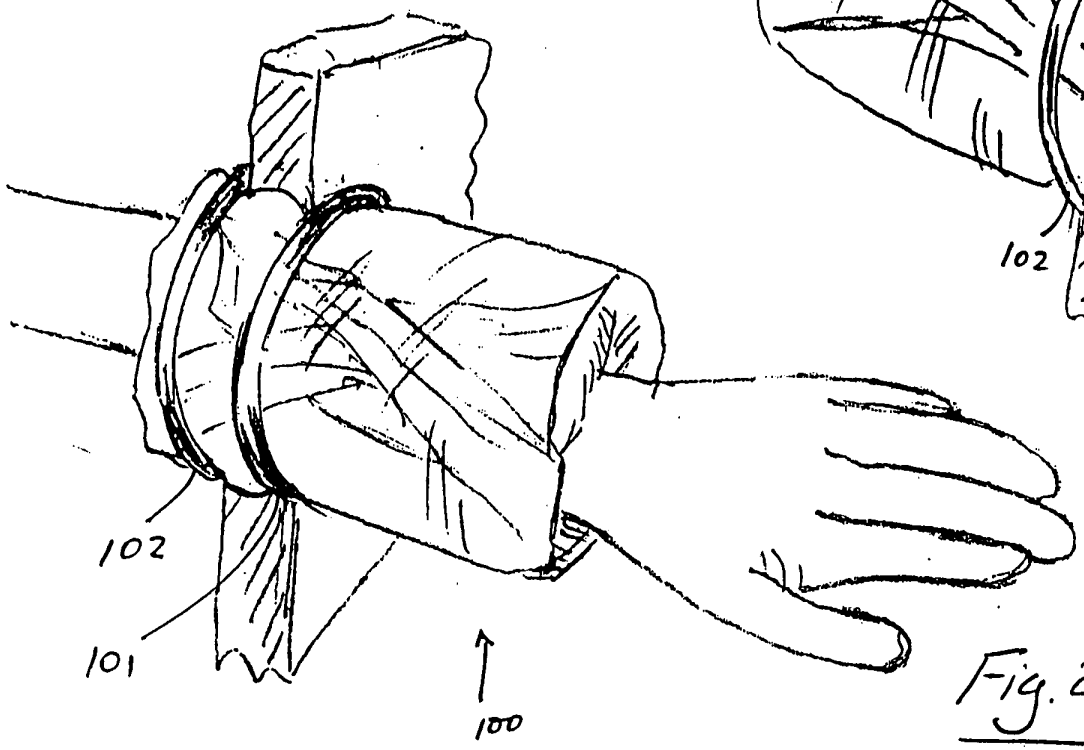


Fig. 26

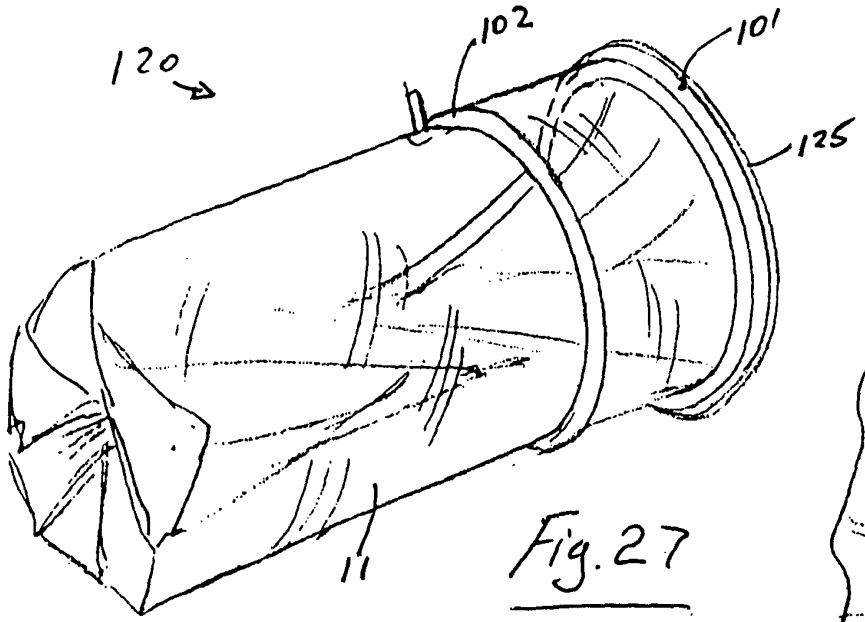


Fig. 27

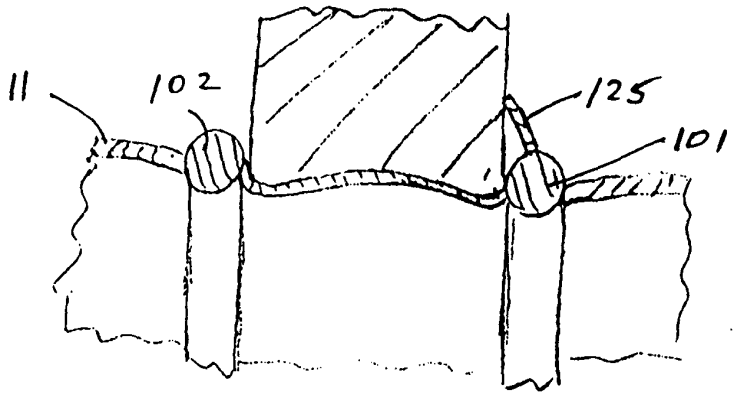


Fig. 29

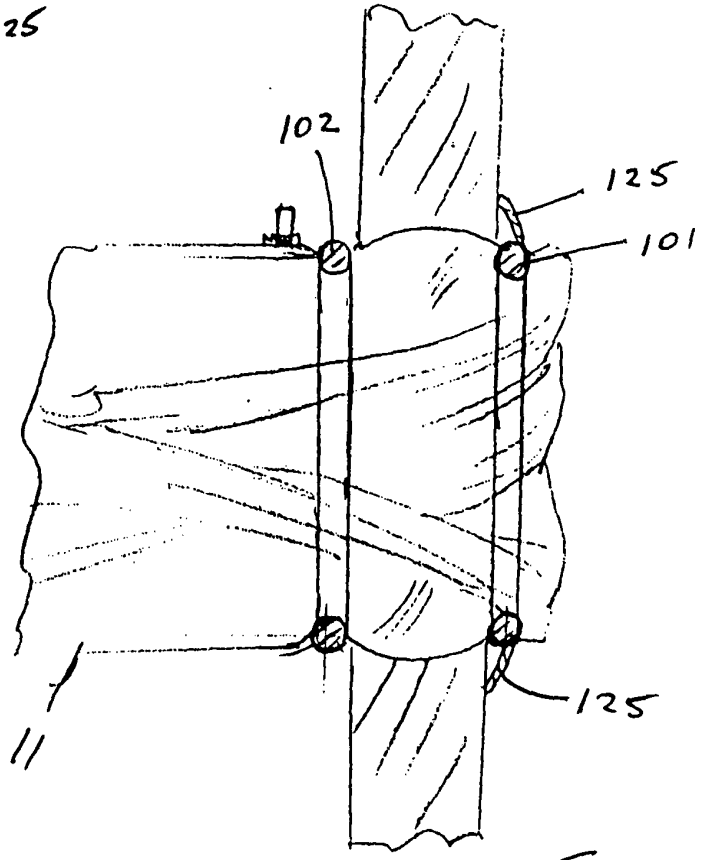


Fig. 28